

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

MERCK SHARP & DOHME CORP.,

Plaintiff,

v.

SANDOZ, INC.,

Defendant.

Civil Action No. 12-3289 (PGS) (LHG)

MEMORANDUM

SHERIDAN, U.S.D.J.

This matter comes before the Court on Defendant Sandoz, Inc.’s (“Sandoz” or “Defendant”) appeal, pursuant to FED. R. CIV. P. 72(a) and L. CIV. R. 72.1(c), of the January 6, 2014 Order entered by the Hon. Lois H. Goodman, U.S.M.J. granting Plaintiff Merck Sharp & Dohme Corp.’s (“Merck” or “Plaintiff”) Motion to Strike Certain Portions of Sandoz’s Expert Report and Denying Sandoz’s Motion to Amend its Invalidity Contentions (ECF No. 142). The Court decides this matter without oral argument pursuant to FED. R. CIV. P. 78(b). For the reasons set forth herein, Magistrate Judge Goodman’s Order of January 6, 2014 is affirmed.

I. BACKGROUND

A. Factual Background

In March 2003, Merck obtained FDA approval for EMEND® Oral, a drug used to treat nausea and vomiting in certain chemotherapy patients and whose active ingredient is aprepitant. (Defs.’ Br. in Supp. of Appeal (“Def.’s Br.”) at 5). In January 2008, Merck obtained FDA approval

for an injectable version of the drug called EMEND® I.V., in which the active ingredient is a prodrug of aprepitant called fosaprepitant. (*Id.*).

On January 24, 2012, Sandoz, in accordance with the procedures established in 21 U.S.C. § 355(j), filed an Abbreviated New Drug Application (“ANDA”) seeking FDA approval to manufacture, use and sell a generic fosaprepitant I.V. product. (*Id.* at 5-6). Sandoz’s ANDA contained a Paragraph IV Certification indicating that the proposed generic product would not infringe U.S. Patent No. 5,691,336 (“the ’336 patent”), the patent covering the fosaprepitant prodrug in EMEND® I.V. (*Id.* at 6). Four months later, on April 23, 2012, Sandoz sent a Paragraph IV Notice Letter informing Merck that it had filed an ANDA with the FDA and stating its belief that the ’336 patent was invalid for obviousness under 35 U.S.C. § 103. (Pl.’s Mem. in Opp’n to Def.’s Appeal (“Pl.’s Opp’n Mem.”) at 4). In its Notice Letter, Sandoz alleged that Merck’s ’336 patent admitted that a Merck foreign patent application, WO’679, was prior art, and that fosaprepitant was obvious in light of WO’679 and a patent and article by Murdock.

On May 31, 2012, within forty-five days of receiving Sandoz’s ’336 patent Paragraph IV Notice Letter, Merck commenced this action by filing a two-count Complaint in the United States District Court for the District of New Jersey. In Count One of its Complaint, Merck asserts that “[b]y seeking approval of its ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the ’336 patent before its expiration including its patent term extension, Sandoz has infringed the ’336 patent pursuant to 35 U.S.C. § 271(e)(2)(A).” (Compl. at ¶ 16). In Count Two, Plaintiff asserts that Sandoz’s proposed manufacture, use or sale of a generic fosaprepitant I.V. product similarly infringed U.S. Patent No. 5,716,942 (“the ’942 patent”).¹ The Court conducted an Initial Pretrial Scheduling Conference on October 2, 2012 during which the parties discussed the

¹ On May 14, 2013, the Court dismissed Plaintiff’s ’942 patent infringement claim without prejudice pursuant to a Stipulation and Order submitted by the parties. (ECF No. 93). Accordingly, Plaintiffs infringement claims are limited to the ’336 patent.

schedule for the case, including the need to complete proceedings prior to the July 2015 expiration of the FDA-imposed stay of approval. Two days later, on October 4, 2012, the Court issued a Pretrial Scheduling Order.

On October 16, 2012, pursuant to the directive of the Court's October 4, 2012 Pretrial Scheduling Order and in accordance with this Court's Local Patent Rules, Sandoz served Merck with its Preliminary Invalidity Contentions for the '336 patent. According to Sandoz, its Invalidity Contentions "explained that several of Merck's own prior art publications . . . disclosed apreipitant." (Def.'s Br. at 6). Furthermore, the Invalidity Contentions "explained why making a prodrug version of that drug – *e.g.*, fosapreipitant – was unpatentably obvious." (*Id.*). The Invalidity Contentions identified nine pieces of alleged prior art and stated that they "incorporate[d] by reference" the contentions of Defendant Accord "to the extent those contentions are not inconsistent with the positions taken [by Sandoz]." ² (Def.'s Preliminary Noninfringement and Invalidity Contentions for the '336 Patent ("Def.'s Invalidity Contentions") at 3). Pursuant to L. Pat. R. 3.3(c), Sandoz also served Merck with a chart identifying four of the alleged prior art documents. (Pl.'s Opp'n Mem. at 6-7).

Prior to Merck serving its Responses to Sandoz's Invalidity Contentions, the parties met and conferred about the scope of those contentions. (*Id.* at 7). According to Plaintiff, Merck expressed concerns "that Sandoz had used vague and confusing language and was attempting to improperly incorporate invalidity contentions of co-defendant Accord without specifically disclosing what they were." (*Id.*). Sandoz maintained that its contentions fully complied with the requirements imposed by L. Pat. R. 3.3 because Sandoz had "provided a narrative portion and claim chart that contain[ed]

² Merck had also filed suit against Defendants Accord Healthcare, Inc. U.S.A., Accord Healthcare, Inc., and Intas Pharmaceuticals, Ltd. on June 1, 2012, alleging that their proposed manufacture, use and sale of a generic fosapreipitant I.V. product would infringe the '336 patent. On June 25, 2013, however, Accord withdrew its Local Patent Rule Invalidity Contentions and agreed to be bound by the '336 patent unless proven invalid in the instant case.

citations and quotes from each reference that Sandoz is relying upon for its obviousness position.” (Pl.’s Mot. to Strike at 2, Ex. 5). Sandoz further maintained that “[t]he prior art combinations on which [it] may rely [were] also set forth in that chart and/or narrative, and include[d] every permutation of the art listed for each claim limitation.” (*Id.*). In response to Merck’s concerns regarding the incorporation by reference of Accord’s Invalidity Contentions, Sandoz maintained that “there is nothing improper about Sandoz’s incorporation by reference . . . [as] [Merck] already ha[d] those in writing[.]” (*Id.*). On November 30, 2012, Merck served its L. Pat. R. 3.4A Responses to Sandoz’s Invalidity Contentions explaining in detail why Sandoz failed to meet its burden to establish a *prima facie* case of obviousness. Merck also explained that Sandoz had improperly attempted to incorporate the Invalidity Contentions of Accord without specifically disclosing them as required under L. Pat. R. 3.3.

On January 5, 2013, Sandoz retained Dr. David H. Sherman to serve as an expert in this matter. On April 5, 2013, pursuant to the provisions of a Protective Order issued by Magistrate Judge Goodman, Sandoz identified Dr. Sherman as its expert and requested that he be permitted to receive and review confidential information produced by Merck as part of this litigation. On May 9, 2013, Merck moved to disqualify Dr. Sherman as an expert based on an alleged conflict of interest and “the manner in which he was retained by Sandoz and ultimately disclosed to Merck.” (Pl.’s Ltr. of May 9, 2013 at 1). On May 21, 2013, Magistrate Judge Goodman denied Plaintiff’s motion. Fact discovery subsequently closed on June 28, 2013.

On August 7, 2013, Sandoz served the expert report of Dr. Sherman (the “Sherman Report”), which included sixteen prior art references that were not previously disclosed in Defendant’s October 16, 2012 Invalidity Contentions. According to Defendant, “Dr. Sherman’s report included, among others, fifteen references that were either incorporated therein by reference or more recently

discovered by Dr. Sherman when drafting his report.” (Def.’s Br. at 7). Defendant states that “[f]our of those references were taken directly from the asserted patent, and *Merck* even cited to them . . . during patent prosecution.”³ (*Id.*) (emphasis in original). The remaining eleven references at issue were allegedly discovered by Dr. Sherman “in July, shortly before his August report, as part of the undertaking experts are expected to perform in patent litigation.” (*Id.*). Dr. Sherman used all fifteen references to respond to arguments raised in Merck’s Responses to Sandoz’s Invalidity Contentions. (*Id.*).

After Merck notified Sandoz of its objection to the inclusion of these additional prior art references absent a motion to amend, the parties met and conferred. The meet and confer process ultimately failed and Sandoz declined to seek leave to amend at that time. As a result, on September 13, 2013, Merck moved to strike those portions of Dr. Sherman’s report which referenced the previously undisclosed prior art. On October 10, 2013, Magistrate Judge Goodman heard oral argument on the motion to strike. At the conclusion of argument, the Court permitted Defendant to seek leave to amend its Invalidity Contentions. (*See* Oct. 10, 2013 Hearing Tr. at 42:24-43:23).

On October 17, 2013, pursuant to the Court’s instructions, Sandoz filed a motion to amend its Invalidity Contentions to include the fifteen prior art references.⁴ In support of its motion, Sandoz argued that “[a]ll three elements required to amend contentions – good cause, timeliness and lack of undue prejudice – exist[ed.]” (Def.’s Mot. to Am. at 1). In regards to the first requirement, Defendant contended that good cause existed to add all fifteen references because: (1) “eleven of the references were only discovered by Sandoz’s expert . . . a few weeks before they were disclosed to

³ Sandoz identifies these references as: (1) WO 93/01169; (2) Edmonds-Alt, et al., *A Potent and Selective Non-Peptide Antagonist of the Neurokinin A (NK2) Receptor*, 50 LIFE SCI PL101 (1992); (3) EPO 0,360,390; and (4) Varia, et al., *Phenytoin Prodrugs III: Water-Soluble Prodrugs for Oral and/or Parenteral Use*, 73(8) J. PHARM. SCI. 1068 (1984). (Def.’s Br. at 7 n.3).

⁴ While the Sherman Report originally included sixteen new prior art references, Defendant decided not to “seek[] leave to amend its contention as to the Magnevist reference.” (Def.’s Mot. to Am. at 1 n.1).

Merck in . . . [the] expert report[,]” and (2) “Sandoz disclosed its reliance on the remaining four references when it told Merck on the day invalidity contentions were served that it intended to rely on prior art cited in the text of the ’336 Patent in suit.” (*Id.* at 1-2). In regards to the timeliness requirement, Defendant argued that “[a]ll of the references were either incorporated into Sandoz’s original contentions . . . or disclosed as part of Dr. Sherman’s expert report within weeks after they were located.” (*Id.* at 2). According to Sandoz, although it “did not file a motion to amend at the precise time it learned of the references (and instead timely disclosed them in an expert report), Merck was well aware of how Sandoz intended to rely on the references[.]” (*Id.*). In regards to the third requirement, Sandoz argued that Merck had failed to articulate any undue prejudice that would result from the proposed amendments. According to Sandoz, the proposed amendments did not require any new discovery or alteration of the case schedule and were fully consistent with Sandoz’s initially served contentions. Moreover, in Sandoz’s view, “there ha[d] been ample time – two months – for Merck to make any adjustment necessary in any rebuttal expert reports it intend[ed] to serve.” (*Id.*). Sandoz further explained that “Merck’s motion to strike portions of Dr. Sherman’s report still require[d] proof of prejudice, which[, it contended,] Merck ha[d] not established.” (*Id.* at 7). As such, Sandoz posited that even if “Sandoz’s motion [to amend] [was] denied, that d[id] not mean that the corresponding portions of Dr. Sherman’s report should automatically be stricken.” (*Id.*).

Merck filed its Opposition to Defendant’s motion on October 24, 2013. In its opposition, Merck argued that Sandoz’s motion to amend should be denied for several reasons. Merck first argued that Sandoz had no reason to delay raising the four uncharted pieces of art allegedly mentioned in the ’336 patent as a basis for its obviousness defense because “Sandoz ha[d] been aware of the ’336 patent since at least January 2009, when it asserted that Merck’s patent claiming

aprepitant was invalid in view of the '336 patent.” (Pl.’s Opp’n to Def.’s Mot. to Amend (“Pl.’s Opp’n to Mot. to Amend”) at 9). According to Merck, Sandoz’s assertion of having conducted a diligent search was, therefore, undermined by Sandoz’s admission that the four pieces of alleged prior art were previously cited in the '336 patent.

Merck next argued that Sandoz’s vague reference to the entirety of the '336 patent did not adequately notify Merck of Sandoz’s intention to rely on the four pieces of alleged prior art contained therein because the '336 patent cited to more than fifty documents and Sandoz did not specifically identify the documents on which it was relying as required by L. Pat. R. 3.3. (*Id.* at 10). According to Merck, “after mentioning the '366 patent as a whole, Sandoz’s contentions discuss[ed] in the narrative sections the scope and content of the alleged prior art that Sandoz relied upon and charted; none of that discussion involve[d] the [fifteen] new alleged prior art references Sandoz now seeks to add.” (*Id.*). Furthermore, Merck asserted that Sandoz’s later representation – in an October 31, 2012 e-mail to Merck – confirmed that the prior art references on which Sandoz relied were the documents discussed in the narrative and/or chart portion of its Invalidity Contentions, neither of which discussed the fifteen pieces of alleged prior art. (*Id.*).

In addition, Merck argued that Sandoz failed to conduct a diligent search to earlier identify the eleven uncharted references allegedly discovered by Dr. Sherman in July 2013.⁵ Plaintiff contended that, “[a]t a minimum, a thorough search and review should have been conducted when Sandoz’s L. Pat. R. 3.3 contentions were first due in October 2012, some six months after its Paragraph IV Notice Letter.” (*Id.* at 10). According to Plaintiff, “[d]iligence is not measured from

⁵ Merck further contended that Sandoz’s assertion about when Dr. Sherman “discovered” the uncharted references was also “demonstrably false.” (Pl.’s Opp’n to Mot. to Amend at 10). According to Plaintiff, Dr. Sherman had previously provided expert testimony based on some of the very same references which he allegedly “discovered” in July 2013 in an earlier trial before Judge Linares. As a result, Merck contended that Sandoz’s claim of diligence for these “references [was] either deliberately false or reckless[.]” regardless of whether the Court looked to Sandoz’s diligence or that of Dr. Sherman. (*Id.* at 11).

when an expert allegedly ‘discovers’ the information[,]” but rather, “is measured from the time that Sandoz should have uncovered the information.” (*Id.* at 11). Plaintiff contended that “[i]n a Hatch-Waxman action, that period should start before the litigation begins, or at the latest, when the Local Patent Rule invalidity contentions are served.” (*Id.*). Merck suggested that a good cause inquiry focused on the diligence of an expert improperly “transposes [a party’s] own diligence requirement onto its expert[.]” (*Id.*). Even if the Court focused its inquiry on Dr. Sherman’s diligence, Merck argued that Sandoz’s motion should still be denied because Dr. Sherman “waited approximately six months to ‘discover’ alleged prior art – and Sandoz waited an additional three months . . . to seek leave to amend its contentions.” (*Id.* at 12).

While Sandoz argued that the uncharted prior art was being introduced to rebut Merck’s November 30, 2012 Responses to its Invalidity Contentions, Merck contended that this argument “prove[d] a lack of diligence[] because Merck’s contentions were available eight months before Sandoz’s expert report[]” was served. (*Id.*). Moreover, Merck suggested that Sandoz was “speak[ing] out of both sides of its mouth when arguing on the one hand that the [fifteen] uncharted references are merely ‘complementary’ background and on the other hand that they are ‘important’ to Sandoz’s obviousness defense.” (*Id.* at 13). According to Merck, if Sandoz had truly considered the references “important” to its obviousness defense, “they should have been disclosed in its original contentions.” (*Id.*). Finally, Merck contended that Sandoz’s decision to wait nearly ten months before seeking leave to amend its invalidity contentions was inexcusable in light of the fact that Merck had informed Sandoz during the parties’ meet and confers leading up to Merck’s Motion to Strike “that the appropriate action was for it to move to amend its contentions.” (*Id.* at 14). On October 29, 2013, Sandoz filed its reply.

On January 6, 2014, Magistrate Judge Goodman issued an Order denying Sandoz's Motion to Amend its Invalidity Contentions and granting Merck's Motion to Strike Certain Portions of the Sherman report insofar as that motion sought to exclude discussion of the fifteen prior art references at issue. *See Merck Sharp & Dohme Corp. v. Sandoz, Inc.*, 2014 U.S. Dist. LEXIS 37002 (D.N.J. Jan. 6, 2014). The Court first addressed Sandoz's argument that it met its disclosure obligations under L. Pat. R. 3.3 with respect to the four pieces of prior art cited in the '336 patent by advising Merck, in its Invalidity Contentions, that it intended to rely on all of the prior art referenced in the patent in issue. The Court rejected Sandoz's argument finding that "[a] general incorporation by reference of more than 50 prior art references in the '336 [p]atent simply does not meet the high standard set by Rule 3.3." *Id.* at *17. Relying on this Court's decision in *AstraZeneca AB v. Hanmi USA, Inc.*, 2012 U.S. Dist. LEXIS 175666, at *19-20 (D.N.J. Dec., 12, 2012), the Court found that "[b]ased on the record, Sandoz has not met its burden of showing that one reasonably skilled in the art would understand [Sandoz's] incorporation to reference the four specific prior art publications at issue." *Merck*, 2014 U.S. Dist. LEXIS 37002 at *17-18.

The court next addressed Sandoz's argument that it was not required to amend its Invalidity Contentions in order to assert the fifteen prior art references as bases for its obviousness defense. After reiterating that it had made clear at the October 10, 2013 hearing that the proper way to proceed was by a motion for leave to amend the invalidity contentions, the Court explained that such a course of action is clearly contemplated by the Local Patent Rules. The Court stated:

The Rules clearly contemplate a situation in which discovery or further investigation by a party, including by the party expert, may lead to the need to expand the invalidity contentions. Specifically, Rule 3.7 sets forth the mechanism for such an amendment. *Id.* at *19.

According to the Court, "[b]y choosing not to seek leave to amend but to instead insert the New Prior Art in its expert report, Sandoz essentially put the burden on Merck to show why it should not

be allowed, rather than bearing the burden itself under Rule 3.7 to show why the amendment should be allowed.” *Id.* Accordingly, the Court found that Sandoz was required to seek leave to amend its Invalidity Contentions and that its attempt to introduce the fifteen prior art references through its expert report was impermissible under L. Pat. R. 3.7.

Having determined that Sandoz was required to seek leave to amend its Invalidity Contentions, the Court next considered whether Sandoz had established good cause for amendment. The Court emphasized that “[t]he key and primary consideration in determining the existence of good cause is the diligence of the moving party[,]” and suggested that “the court does not even reach the issue of whether the proposed amendment would prejudice the non-moving party[]” if the moving party fails to establish its diligence in finding new information or seeking leave to amend. *Id.* at *20. After considering Defendant’s arguments, the Court found that Sandoz had failed to meet its burden of establishing good cause because it failed to demonstrate its diligence in finding the fifteen additional prior art references. According to the Court, “[o]ther than accounting for the time during which Merck sought to preclude Sandoz’s reliance on Dr. Sherman as an expert in this case, Sandoz does not explain what it was doing between November 2012 and July 2013 to develop a rebuttal to Merck’s Response, and why it could not have uncovered the New Prior Art earlier.” *Id.* at *20 (citing *O2 Micro Int’l, Ltd. v. Monolithic Power Sys.*, 467 F.3d 1355, 1367 (Fed. Cir. 2006)). Because the Court found that Sandoz did not meet its burden of showing that it was diligent in seeking to discover the fifteen additional prior art references, it did not address, as part of its Motion to Amend analysis, whether Merck would be prejudiced by the proposed amendment. *Merck*, 2014 U.S. Dist. LEXIS 37002 at *23-24. In light of its determination that Sandoz was required to introduce those references via amendment, and not through its expert report, the Court also granted

“Merck’s motion to strike those portions of Dr. Sherman’s report that rely on or reference the New Prior Art.” *Id.* at *24.

The Court ordered a scheduling conference in this matter for January 14, 2014 to discuss deadlines for the completion of expert discovery and the filing of dispositive motions. During that conference, Sandoz expressed its intention to appeal Magistrate Judge Goodman’s January 6, 2014 Order and requested that the Court either issue a stay of the case or allow Sandoz to proceed with the current version of its expert report. On January 17, 2014, Magistrate Judge Goodman issued a Letter Order staying expert discovery until April 15, 2014 and rescheduling trial for January 5, 2015. On January, 21, 2014, Sandoz filed the instant appeal.

II. DISCUSSION

A. Standard of Review

A magistrate judge may hear and determine any non-dispositive pretrial matter pending before the district court. *See* 28 U.S.C. § 636(b)(1)(A). The district court will only modify or set aside a magistrate judge’s decision on these matters if it is “clearly erroneous or is contrary to law.” FED. R. CIV. P. 72(a); *see also* L. Civ. R. 72(c)(1)(A) (stating that a district court judge “shall consider the appeal and/or cross-appeal and set aside any portion of the Magistrate Judge’s order found to be clearly erroneous or contrary to law.”). A district court will, therefore, “review a magistrate judge’s findings of fact for clear error.” *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, 2013 U.S. Dist. LEXIS 28374, at *3 (D.N.J. Feb. 28, 2013) (citing *Lithuanian Commerce Corp. v. Sara Lee Hosiery*, 177 F.R.D. 205, 213 (D.N.J. 1997) (internal quotations omitted); *see also Janssen Prods., L.P. v. Lupin, Ltd.*, 2013 U.S. Dist. LEXIS 85192, at *5 (D.N.J. June 18, 2013).

A finding is considered “clearly erroneous” when, “although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake

has been committed.” *United States v. United States Gypsum Co.*, 333 U.S. 364, 395, 68 S. Ct. 525, 92 L. Ed. 746 (1948). A decision is considered contrary to law if the magistrate judge has “misinterpreted or misapplied applicable law.” *Doe v. Hartford Life Acc. Ins. Co.*, 237 F.R.D. 545, 548 (D.N.J. 2006). The district court “will not reverse the magistrate judge’s determination, even in circumstances where the court might have decided the matter differently.” *Janssen Prods.*, 2013 U.S. Dist. LEXIS 85192 at *6 (citing *Bowen v. Parking Auth. of City of Camden*, 2002 U.S. Dist. LEXIS 14582, at *3 (D.N.J. July 30, 2002)). Moreover, “[a] district judge’s simple disagreement with the magistrate judge’s findings is insufficient to meet the clearly erroneous standard of review.” *Andrews v. Goodyear Tire & Rubber Co.*, 191 F.R.D. 59, 69 (D.N.J. 2000).

The Federal Circuit had stated, and decisions of this Court have affirmed, that “[d]ecisions enforcing local rules in patent cases will be affirmed unless clearly unreasonable, arbitrary, or fanciful; based on erroneous conclusions of law; clearly erroneous; or unsupported by any evidence.” *O2 Micro Int’l, Ltd.*, 467 F.3d at 1366-67 (citing *Genetech, Inc. v. Amgen, Inc.*, 289 F.3d 761, 774 (Fed. Cir. 2002); *see also Novartis Pharms., Corp. v. Wockhardt USA LLC*, 2013 U.S. Dist. LEXIS 125265, at *9 (D.N.J. Sept. 3, 2013).

B. Defendant’s Motion to Amend its Invalidity Contentions Pursuant to L. Pat. R. 3.7

The Local Patent Rules “‘exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases.’” *TFH Publ’ns, Inc. v. Doskocil Mfg. Co., Inc.*, 705 F. Supp. 2d 361, 365 (D.N.J. 2010) (quoting *Computer Acceleration Corp. v. Microsoft Corp.*, 503 F. Supp. 2d 819, 822 (E.D. Tex. 2007). They emphasize “ultra early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch-Waxman Act.” *Sanofi-Aventis v. Barr Labs.*, 598 F. Supp. 2d 632, 637 (D.N.J. 2009).

Pursuant to L. Pat. R. 3.7, a party may amend its infringement or invalidity contentions “only by order of the Court upon a timely application and showing of good cause.” L. Pat. R. 3.7. A court may permit a party to amend its invalidity contentions provided the following three elements are established: “(1) the moving party makes a timely application to the court; (2) there is good cause for the amendment; and (3) there is no undue prejudice to the adverse party.” *AstraZeneca AB v. Hanmi USA, Inc.*, 2013 U.S. Dist. LEXIS 8939, at *4 (D.N.J. Jan. 23, 2013) (citing *Jazz Pharms., Inc. v. Roxane Labs., Inc.*, 2012 U.S. Dist. LEXIS 107408, at *6 (D.N.J. July 30, 2012)). The rule is “designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed.” *King Pharms., Inc. v. Sandoz, Inc.*, 2010 U.S. Dist. LEXIS 50163, *10 (D.N.J. May 20, 2010) (citing *Atmel Corp. v. Info. Storage Devices, Inc.*, 1998 U.S. Dist. LEXIS 17564, at *7 (N.D. Cal. Nov. 5, 1998)).

“Distinguishable from the liberal standard for amending the pleadings, ‘the philosophy behind amending claim charts is decidedly conservative, and designed to prevent the “shifting sands” approach to claim construction.’” *Id.* L. Pat. R. 3.7, however, “is not a straightjacket into which litigants are locked from the moment their contentions are served.” *Comcast Cable Commc’ns Corp. v. Finisar Corp.*, 2007 U.S. Dist. LEXIS 98474, at *5 (N. D. Cal. Mar. 2, 2007). Rather, “[t]here is a modest degree of flexibility, *at least near the outset.*” *Id.* (emphasis added). Therefore, “while ‘preliminary infringement contentions are still preliminary[,]’ it is important to recognize that the Local Patent Rules strive to have the parties establish their contentions early on.” *King Pharms., Inc.*, 2010 U.S. Dist. LEXIS 50163 at *11 (quoting *General Atomics v. Axis-Shield ASA*, 2006 U.S. Dist. LEXIS 58939, at *6 (N.D. Cal. Aug. 9, 2006)).

With regard to the “good cause” requirement, the Federal Circuit has stated that parties must “proceed with diligence in amending [their] contentions when new information comes to light in the

course of discovery.” *O2 Micro Int’l, Ltd.*, 467 F.3d at 1366-67. The “moving party has the burden of demonstrating its diligence . . . and must show that it was both diligent throughout discovery and in ‘discovering the basis for the proposed amendment.’” *Janssen Prods., L.P.*, 2013 U.S. Dist. LEXIS 85192, at *8 (quoting *West v. Jewelry Innovations, Inc.*, 2008 U.S. Dist. LEXIS 84928, at *7 (N.D. Cal. Oct. 8, 2008)).

Defendant argues that Magistrate Judge Goodman’s denial of Sandoz’s Motion to Amend its Invalidity Contentions is clearly erroneous and contrary to law for two reasons. First, Defendant contends that Magistrate Judge Goodman erred by failing to consider that Merck had notice of the four pieces of alleged prior art cited in the prosecution of the ‘336 patent and that Sandoz incorporated by reference into its October 16, 2012 Invalidity Contentions. (Def.’s Br. at 18-20). Second, Defendant contends that Magistrate Judge Goodman erred “by failing to find that the one month between discovery of the remaining references by Dr. Sherman in July 2013 and their disclosure on August 7, 2013, satisfies the diligence requirement needed to grant Sandoz’s motion to amend.” (*Id.* at 21). The Court will address of these arguments in turn.

With respect to its first argument, Merck argues that Magistrate Judge Goodman “erred as a matter of law when [she] refused to even consider Merck’s prior notice of the four references *that Merck had cited to the USPTO during prosecution of the asserted patent.*” (Def.’s Br. at 18) (emphasis in original). In support of its argument that good cause to amend its Invalidity Contentions existed, Defendant cites the case of *V.Mane Fils S.A. v. Int’l Flavors & Fragrances, Inc.*, 2011 U.S. Dist. LEXIS 38637, at *8 n.10 (D.N.J. Apr. 8, 2011) for the proposition that “[a]mendment may be permitted where, although the moving party did not revise its formal infringement or invalidity contentions in a timely manner, its adversary nevertheless had adequate notice of the substance of the moving party’s position[.]” While Defendant argues that the Court “refused to even consider

Merck's prior notice of the four references[.]" a reading of Magistrate Judge Goodman's Order suggests otherwise. The Court did not, as Defendant suggests, simply disregard the *V.Mane* case and the effect an adversary's prior notice has on a moving party's ability to amend its invalidity contentions. Rather, the Court found the case distinguishable and Defendant's related notice argument unpersuasive. *See Merck*, 2014 U.S. Dist. LEXIS 37002, at *23 (stating that "[t]he language relied upon by Sandoz, found in *V.Mane*[] . . ., is in a footnote, referencing a Southern District of New York case in which the proposed amendments related to two affidavits from an expert disclosed at the time of the *Markman* hearing, years before the motion to amend and much earlier than in the present case."). Defendant is simply incorrect in asserting that the Court neglected to consider the effect of Merck's alleged prior notice as part of its good cause analysis.

In specifically rejecting Sandoz's notice argument, Judge Goodman wrote that "Sandoz err[ed] in arguing that adequate notice can mitigate a party's burden to proceed with diligence." *Id.* at *23. In stating so, the Court recognized that notice is not dispositive in establishing good cause and does not excuse a patent challenger from diligently fulfilling its disclosure obligations under the Local Patent Rules. Here, Magistrate Judge Goodman found that Sandoz's generic introductory statement in its Invalidity Contentions purporting to cite to the entirety of the '336 patent, its prosecution history, and the prior art cited in the patent did not satisfy Sandoz's disclosure obligations under the L. Pat. R. 3.3. *See id.* at *17 (stating that "[a] general incorporation by reference of more than 50 prior art references cited in the '336 patent simply does not meet the high standard set by Rule 3.3."). As such, the Court determined that Sandoz was obligated to seek leave to amend its Invalidity Contentions in order to include the four alleged prior art references as part of its obviousness defense. After considering the parties' arguments, including Sandoz' notice argument, and reviewing the applicable law, Magistrate Judge Goodman concluded that by failing to

seek leave to amend until October 2013, Sandoz had failed to meet its burden of showing diligence with respect to the four alleged prior art references. This Court finds no error in Magistrate Judge Goodman's finding. *See O2 Micro Int'l, Ltd.*, 467 F.3d at 1366-67; *see also Jazz Pharms., Inc.*, 2013 U.S. Dist. LEXIS 28374 at *7-8.

With respect to its second argument, Sandoz argues that Magistrate Judge Goodman also "erred by failing to find that the one month between discovery of the remaining references by Dr. Sherman in July 2013 and their disclosure on August 7, 2013, satisfies the diligence requirement needed to grant Sandoz's motion to amend." (Def.'s Br. at 21). According to the Defendant, "[e]ven the roughly two months between when Sandoz was allowed to fully work with Dr. Sherman after the May 21, 2013 denial of Merck's motion to disqualify and his August expert report should be satisfactory to add the other eleven references to Sandoz's contentions." (*Id.*).

The Court affirms Magistrate Judge Goodman's finding that Defendant did not act with the requisite diligence with respect to the eleven additional references allegedly "discovered" by Dr. Sherman because "[t]he party seeking to amend its contentions bears the burden of establishing diligence." *West*, 2008 U.S. Dist. LEXIS 84928 at *4 (citing *O2 Micro Int'l, Ltd.*, 467 F.3d at 1366-67). Magistrate Judge Goodman found that Defendant failed to meet such a burden, and this Court sees no error in such finding.

In order to establish diligence, "not only must [a] party prove that it was diligent throughout the course of discovery, but also that it was diligent in its search for relevant prior art." *Jazz Pharms., Inc.*, 2013 U.S. Dist. LEXIS 28374 at *7 (citing *West*, 2008 U.S. Dist. LEXIS 84928 at *6). Thus, "a party's diligence in amending its preliminary invalidity contentions upon finding new prior art is only one factor to consider; the Court also must address whether the party was diligent in discovering the basis for the proposed amendment." *Id.* Here, as Magistrate Judge Goodman

properly recognized, “[o]ther than accounting for the time during which Merck sought to preclude Sandoz’s reliance on Dr. Sherman as an expert in this case, Sandoz does not explain what it was doing between November 2012 [(when Merck served its Responses to Sandoz’s Invalidity Contentions)] and July 2013 [(when Dr. Sherman allegedly discovered the eleven pieces of additional prior art)] to develop a rebuttal to Merck’s Response, and why it could not have uncovered the New Prior Art earlier.” *See Merck*, 2014 U.S. Dist. LEXIS 37002, at *21. While Defendant argues that its ability to conduct a diligent search was hampered by Plaintiff’s motion to disqualify its expert, Sandoz fails to disclose that it had been working with its expert for four months prior to the filing of that motion.

On appeal, Defendant merely restates reasons why it purportedly took almost seven months to discover the eleven addition pieces of alleged prior art and an additional three months from that date to seek leave to amend its Invalidity Contentions. Magistrate Judge Goodman found none of Defendant’s reasons availing, and this Court finds that Judge Goodman did not err in making such a finding. *See Jazz Pharms, Inc.*, 2013 U.S. Dist. LEXIS 28374 at *12 (stating that “mere disagreement with the judicial finding of a Magistrate Judge does not meet the ‘clear error standard’ required for reversal.”) (citing *Walzer v. Muriel Siebert & Co., Inc.*, 2010 U.S. Dist. LEXIS 115245, at *26 (D.N.J. Oct. 28, 2010)). The Court also finds that the Magistrate Judge’s decision is not contrary to law. “Simply because [Sandoz] is able to cite to a few decisions granting leave to amend contentions in the face of comparable delays by the parties seeking amendment does not render the Magistrate Judge’s Order clearly erroneous.” *Janssen Prods., L.P.*, 2013 U.S. Dist. LEXIS 85192 at *12 (citing *Jazz Pharms, Inc.*, 2013 U.S. Dist. LEXIS 28374 at *12). Accordingly, the Court affirms the January 6, 2014 Order denying Defendant’s Motion to Amend its Invalidity Contentions.

C. Plaintiff’s Motion to Strike Certain Portions of Defendant’s Expert Report

Defendant argues that Magistrate Judge Goodman’s grant of Merck’s Motion to Strike Certain Portions of Sandoz’s Expert Report is clearly erroneous and contrary to law for two reasons. First, Defendant contends that, in granting the motion to strike, Magistrate Judge Goodman failed to consider “the complete absence of real, specific and credible prejudice to Merck resulting from the reference to allegedly new prior art in Dr. Sherman’s report[.]” (Def.’s Reply to Pl.’s Opp’n to Def.’s Appeal (“Def.’s Reply”) at 1). Second, Defendant contends that Magistrate Judge Goodman “erred by striking five paragraphs of Dr. Sherman’s report that are unrelated to the art at issue, and are fully supported by other references[.]” (*Id.*).

In her Order, Magistrate Judge Goodman makes clear that her decision to grant Plaintiff’s Motion to Strike was made, “in light of [her] prior determination that the introduction of the New Prior Art should be made in the first instance by amendment, rather than through an expert report[.]” *Merck*, 2014 U.S. Dist. LEXIS 37002 at *24. Having denied Defendant’s Motion to Amend its Invalidity Contentions, Magistrate Judge Goodman reasoned that permitting Defendant to include the fifteen additional prior art references in its expert report would essentially negate the effect of her prior decision and allow Sandoz to skirt the requirements imposed by the Local Patent Rules.

While Defendant now argues that the Court erred by declining to analyze whether Merck would be prejudiced by the inclusion of the fifteen additional prior art references in Sandoz’s expert report, common sense dictates that a party who has been denied leave to amend its invalidity contentions to add certain prior art references should not then be able to circumvent the Court’s Order by presenting those very same prior art references in its expert report as part of its obviousness defense.⁶ *See Pactiv Corp. v. Multisorb Techs., Inc.*, 2013 U.S. Dist. LEXIS 75585, at *10 (N.D. Ill.

⁶ In the view of this Court, permitting Sandoz to assert new bases for its obviousness defense for the first time in its expert report, approximately seven months after its Invalidity Contentions had been served, would cause prejudice to Merck by requiring it to spend great time and expense reformulating its Responses to Sandoz’s Invalidity Contentions and rethinking its litigation strategy.

May 9, 2013) (stating that “[t]o allow an expert to go beyond [a patent challenger’s Invalidity Contentions] would render them useless and ignore the specificity requirements of the Local Patent Rule[s.]”); *see also Monolithic Power Sys., Inc. v. O2 Micro Int’l, Ltd.*, 2009 U.S. Dist. LEXIS 101035, at *10 (N.D. Cal. Oct. 16, 2009) (stating that “[b]ecause the Court denied O2 Micro’s motion to amend, it grants this motion to strike.”). Doing so would essentially render the Court’s decision on the Motion to Amend meaningless and frustrate the purpose for which the Local Patent Rules were developed. *See TFH Publ’ns, Inc.*, 705 F. Supp. 2d at 365 (stating that “[t]he Local Patent Rules exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their cases.”) (internal quotations and citation omitted); *see also* L. Pat. R. 3.7(e) (stating that [t]he duty to supplement discovery responses under Fed. R. Civ. P. 26(e) does not excuse the need to obtain leave of Court to amend contentions, disclosures, or other documents required to be filed or exchanged pursuant to these Local Patent Rules.”). Taking Defendant’s argument to the extreme, a patent challenger could “serve barebones contentions, let their adversary litigate through fact discovery based on them, and, without diligence, simply insert new contentions at the time of the expert report[.]” (Pl.’s Opp’n Mem. at 29). This Court does not wish to go down such a slippery slope and Sandoz surely should have sought leave to amend much sooner in order to meet the diligence standard. Therefore, Magistrate Judge Goodman’s decision on Plaintiff’s Motion to Strike was neither clearly erroneous nor contrary to law.

Defendant further contends that “[e]ven if Merck were correct that some portions of Dr. Sherman’s report should be stricken because of improper references to ‘new’ prior art, the January 6, 2014 Order goes far beyond that.” (Def.’s Br. at 17). According to Defendant, Magistrate Judge Goodman’s January 6, 2014 “is clearly erroneous as it grants all of Merck’s proposed redactions concerning the ‘new alleged prior art,’ even where the proposed redactions have nothing to do with

the reasoning of the Order.” (*Id.*). Sandoz specifically identifies five paragraphs of its expert report (175, 200, 201, 203 and 206) whose “removal[, it argues,] is not justified by the reasoning of the Order, or any justifiable reasoning.” (*Id.* at 18). Plaintiff argues in opposition that those “paragraphs plainly refer to the prior art for which leave to amend was denied.” (Pl.’s Opp’n Mem. at 31). After considering the arguments of the parties, and reviewing the five paragraphs in issue, this Court finds that Magistrate Judge Goodman’s Order, which strikes those five paragraphs, is neither clearly erroneous nor contrary to law. The remedy ordered by the Court falls within the discretion of the Magistrate Judge and this Court is reluctant to substitute its judgment for that of the Magistrate, who has managed discovery proceedings since the inception of this litigation, absent clear error. Accordingly, the Court affirms the January 6, 2014 Order granting Plaintiff’s Motion to Strike Certain Portions of Defendant’s Expert Report.

III. CONCLUSION

For the reasons set forth above, the Court finds that the Magistrate Judge’s Order of January 6, 2014 is not clearly erroneous, unsupported by any evidence or contrary to law. Accordingly, the January 6, 2014 Order is affirmed. An appropriate Order follows.

Date: April 16, 2014

s/Peter G. Sheridan
PETER G. SHERIDAN, U.S.D.J.